QA: QA

U. S. DEPARTMENT OF ENERGY OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT OFFICE OF QUALITY ASSURANCE

AUDIT REPORT SNL-ARC-02-04

OF

SANDIA NATIONAL LABORATORIES

 \mathbf{AT}

ALBUQUERQUE, NEW MEXICO

JANURY 14-18, 2002

Prepared by:		Date:		
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	Audit Team Leader			
	Navarro Quality Services			
Approved by:	!	Date:		
	Ram Murthy			
	Acting Director			
	Office of Quality Assurance			

1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Audit SNL-ARC-02-04, the audit team determined that the Sandia National Laboratories (SNL) located in Albuquerque, New Mexico is satisfactorily and effectively implementing the applicable portions of the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM) QA Program in accordance with DOE/RW-0333P, Revision 10, *Quality Assurance Requirements and Description* (QARD), OCRWM program procedures and SNL implementing procedures.

Good Practices

Engineering Assurance provided each SNL staff member a copy of their Training Matrix and Training Status Report from the Training Server. Staff members that were interviewed during the audit had their Training Matrix available and knew the status of their training assignments.

The Engineering Assurance designee assembled folders for each employee, consisting of the Training Matrix (Revision 2), Training Status Report from the Training Server, Position Description and completed Verification of Education and Experience form. This provided SNL management assurance that all employees were current in regards to Training, Position Description, and Verification of Education and Experience. In addition, it demonstrated compliance during the audit.

The SNL Measuring and Test Equipment Custodian involved the QA On-Site Representative in the review and acceptance of the Calibration Certificates and the required Acceptance Report, which they both signed. This helped to ensure an acceptable process.

In addition, the effectiveness of corrective actions related to five previously closed Deficiency Reports (DR) were evaluated with satisfactory results. The details are described in paragraph 5.5.5.

2.0 SCOPE

Auditors representing the DOE's Office of Quality Assurance (OQA) conducted a compliance audit to evaluate SNL's implementation of the OCRWM QA Program as described in the QARD and applicable implementing procedures at the SNL facilities. In addition, observers representing the Clark County, Nevada Department of Comprehensive Planning, and Fluor Hanford Analytical Services observed the audit.

The audit team, through interviews of cognizant personnel, reviews of documentation, and evaluation of procedures, assessed implementation, adequacy, and effectiveness of SNL's implementation of the QA Program.

In addition, the audit team also reviewed recently closed OCRWM deficiency documents of SNL activities to determine the effectiveness of completed corrective actions.

In accordance with the approved audit plan, the following QA Program Sections were evaluated.

1.0	Organization
2.0	Quality Assurance Program
3.0	Design Control
5.0	Implementing Documents
6.0	Document Control
7.0	Control of Purchased Items and Services
12.0	Control of Measuring and Test Equipment
15.0	Nonconformances
16.0	Corrective Action
17.0	Quality Assurance Records
Supplement I	Software
Supplement II	Sample Control
Supplement III	Scientific Investigation
Supplement V	Control of the Electronic Management of Data
Appendix C	Monitored Geologic Repository (as applied to QARD Section 7.0)

The following QA Program Sections were not evaluated, as SNL is currently not implementing them:

4.0	Procurement Document Control
8.0	Identification and Control of Items
9.0	Control of Special Processes
10.0	Inspection
11.0	Test Control
13.0	Handling, Storage, and Shipping
14.0	Inspection, Test, and Operating Status
18.0	Audits
Supplement IV	Field Surveying
Appendix A	High-Level Waste Form Production
Appendix B	Storage and Transportation

3.0 AUDIT TEAM AND OBSERVERS

The following is a list of audit team members and assigned areas of responsibility:

Name/Title/Organization	QA Program Sections			
Donald J. Harris, Navarro Quality Services (NQS)	1.0, 2.0, 7.0, 12.0, and Supp V			
Las Vegas, NV, Audit Team Leader				

Name/Title/Organization

Kristi A. Hodges, NQS, Las Vegas, NV, Auditor F. Harvey Dove, NQS, Las Vegas, NV, Auditor James Blaylock, OQA, Las Vegas, NV, Auditor

QA Program Sections

5.0, 6.0, Supp I and III 2.0, 3.0, and Supp III 2.0, 15.0, 16.0, 17.0, Supp II and III

Observers

Englebrecht von Tiesenhausen, Clark County, NV, Representative Tilak R. Verma, Fluor, Hanford, WA Russ Bisping, Fluor, Handford, WA

4.0 AUDIT TEAM MEETINGS AND PERSONNEL CONTACTED

The pre-audit meeting was held at SNL's offices in Albuquerque, New Mexico on January 14, 2002. Daily debriefings were held to apprise SNL management and staff of the progress of the audit and any conditions adverse to quality. The audit was concluded with a post-audit meeting held on January 18, 2002, at SNL's Albuquerque, New Mexico offices.

Personnel contacted during the audit, including those who attended the pre- and post-audit meetings, are listed in Attachment 1, "Personnel Contacted During the Audit."

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that, overall SNL's implementation of the QA program is adequate and effective. The results for each QA program section evaluated are contained in Attachment 2, "Summary Table of Audit Results."

- 1. Technical Reviews: No concerns were identified during the audit other than a procedure issue that leads one to believe that an AP-2.14Q, Revision 2, *Review of Technical Products and Data*, review of submitted data is completed prior to submittal to the Technical Data Management System database. In actuality, AP-2.14Q reviews are conducted on data from a scientific notebook (SN); however, data is submitted as preliminary if it is an input to a technical product that will be reviewed per AP-2.14Q.
- 2. Procedures: There has been limited activity in the area of procedures and no deficiencies were identified. Procedure changes noted were editorial in nature and required no formal review. SNL utilizes AP-2.14Q for all substantive changes, and has not implemented AP-6.28Q, Revision 0, BSCN 1, *Document Review*.

- 3. Document Control: SNL, as well as all the remote locations, are increasingly relying on electronic documents; therefore, the opportunity for working to a superseded procedure, or failing to update obsolete controlled documents is greatly reduced. The follow-up on DR BSC-01-D-127, which was written based on BSC-ARC-01-08, was not entirely successful because the DR response only addressed controlled documents issued out of BSC, Las Vegas. However, the description of the condition adverse to quality also identified documents controlled by the laboratories and U.S. Geological Survey (USGS). The document holdings at SNL issued from BSC, Las Vegas, were decontrolled, which was coordinated with the BSC document control organization.
- 4. Software: Although there is limited implementation of AP-SI.1Q, Revision 3, ICN 2, *Software Management*, SNL needs to provide specific attention to the area of software in order to preclude future documentation errors and deficiencies. The following issues were addressed during the audit:
 - A request was submitted to the BSC and subsequently approved, to acquire one software code (DATAVE); and, a second request was submitted to acquire ABACUS, which had not yet received approval at the time of the audit. Preliminary qualification documentation for DATAVE, representing initial implementation of AP-SI.1Q, was reviewed during the audit. Although in a draft status, it was apparent that extra attention will be needed in order to successfully complete the qualification process to meet the current requirements.
 - Twelve Level 3 software codes (routines) that had received Software Tracking Numbers and were initiated for qualification as part of DR LVMO-00-D-039 effort, were retracted from Software Configuration Management with a statement on a Software Baseline Request (SBR) that the codes were documented within SNs. During the audit, the twelve SBRs were appended to state that the single-use codes were documented within the technical product. The product (ANL-NBS-TH-000001, Revision 0, ICN 1) was reviewed and verified to include the codes. Note that the appended information clarified the record rather than corrected a deficiency during the audit.
 - Several Level 3 software codes (routines) developed prior to the software stand-down, which is associated with BSC-01-C-002, were not qualified or approved for interim use. These codes were not used in any product, although they may be used in a future product. Essentially, approval for interim use may have been appropriate, but the software stand-down pre-empted further processing. There is no apparent deficiency in the status of the codes; however, a path forward to move them from this status was being discussed by SNL during the audit.

5.2 Stop Work or Immediate Corrective Actions Taken

There were no stop work orders or immediate corrective actions as a result of the audit.

5.3 **QA Program Implementation**

Attachment 2, "Summary Table of Audit Results," provides results for each QA program section audited. The details of the audit, including the objective evidence reviewed, are documented in the audit checklist. The checklist is maintained as a QA record.

5.4 Technical Audit Activities

There were no technical activities evaluated during this audit.

5.5 Summary of Deficiencies

There were no conditions adverse to quality identified during the audit.

5.5.1 Corrective Action Reports

None.

5.5.2 Deficiency Reports

None.

5.5.3 Deficiency Identification and Referrals

None.

5.5.4 <u>Deficiencies Corrected During the Audit</u>

None.

5.5.5 Follow-up of Previously Identified Conditions Adverse to Quality

Five deficiency documents were evaluated for effectiveness of corrective action.

SNL-00-D-098 - SNL Management failed to ensure training assignments were developed and processed for newly assigned personnel. Effective correction was confirmed by sampling 10 personnel, each had a copy of their Training Matrix and updated Training Status from the Train Server database.

SNL-00-D-109 - The disposition of an Nonconformance Report (NCR) was revised and an approval signature was not obtained. Effective correction was confirmed by review of the NCR database, no NCRs have been issued by SNL or against SNL since September 1, 2000.

SNL-01-D-012 - SN or approved implementing document was not on location during testing. Effective correction was confirmed by review of the DR database and a review of the only SN (in process) in Albuquerque, New Mexico and discussions with the SNL Technical staff.

SNL-01-D-045 - Record packages not submitted to the Records Processing Center (RPC) within the 60-day time frame. Effective correction was confirmed by verifying that the records were being submitted to the RPC as collected. There was no records backlog detected during the audit.

SNL-01-D-123 - SN initial entries were incomplete. Effective correction was confirmed by verification of SNL-SCI-022, Vol. I. The initial entry referenced the Technical Work Plan (TWP), subsequently the TWP changed. The SN was updated by pen and ink changes

BSC-01-D-127 - Document holders possessed superseded documents. The DR response addressed controlled documents issued out of BSC, Las Vegas. However, the description of conditions adverse to quality also identified documents controlled by the laboratories and USGS. Therefore, this DR is being re-evaluated for additional action to resolve the full extent of the identified conditions.

6.0 RECOMMENDATIONS

No recommendations were documented for SNL management consideration.

7.0 LIST OF ATTACHMENTS

Attachment 1 "Personnel Contacted During the Audit"

Attachment 2 "Summary Table of Audit Results"

Attachment 3 "Acronyms/Abbreviations"

ATTACHMENT 1

Personnel Contacted During the Audit

NI	Personnel Contacted During t	Pre-audit	Contacted	Post-audit	
Name	Organization	Meeting	During Audit	Meeting	
James Graff	QA On-Site Representative/BSC	X	X	X	
Richard Powe	On-Site Representative/BSC		X		
Pat Gibson	Document Control/BSC		X		
Engelbrecht von Tiesenhausen	Observer/Clark County	X		X	
Russ Bisping	Observer/Fluor Hanford	X		X	
Tilak Verma	Observer/Fluor Hanford	X		X	
Bill Glasser	QA Specialists/NQS		X		
Bob Hasson	Verification Manager/NQS		X		
Jim Voigt	QA Specialist/NQS		X		
Kathleen Economy	Sat Zone/Management Solutions, LLC		X		
Joe Archuleta	Engineering Assurance Lead/SNL	X	X	X	
Richard Aguilar	Performance Assessment/SNL	X			
Bill Arnold	Principle Technical Staff/SNL	X	X		
Nancy Brodsky	Geomechanics/SNL		X		
David Bronowski	Geomechanics/SNL		X		
Iris Castagna	Records Coordinator/SNL/SAIC	X		X	
John Cochran	TSPA/SNL	X			
Delene Cox	Financial Analysts/SNL	X	X		
Nina Garcia	Records Coordinator/SNL/SAIC	X	X		
Eloise James	Technical Data Coordinator/SNL/SAIC	X	X	X	
Robert Jones	Repository Testing/SNL			X	
Carlos Jove-Colon	TSPA/SNL		X		
Hong-Nian Jow	Manager, Sub Performance Analyses/SNL	X	X	X	
Stephanie Kuzio	Sub Performance Assessment/SNL		X		
Robert MacKinnon	TSPA/SNL		X	X	
Steve Miller	TSPA/SNL		X		
James Nowak	Sub Performance Assessment/SNL		X		
Andrew Orrell	Lab Lead/SNL	X	X	X	
Marie Owens	Science Organization/SNL		X		
James Ramsey	Sub Performance Assessment/SNL		X		
Albert Schenker	Technician/SNL (LATA)	X			
Julia Schneider	Performance Assessment Software Coordinator/SNL	X	X	X	
Sylvia Sweeney	Records Coordinator/SNL/SAIC	X		X	
Peter Swift	Manager, TSPA/SNL	X	X	X	
Ronnie Taylor	M&TE Coordinator/SNL		X		

ATTACHMENT 2 SUMMARY TABLE OF AUDIT RESULTS

QARD Sections	Implementing Documents	Checklist Pages	Deficiencies/ DIRs	CDA	REC	Program Adequacy	Procedure Compliance	Overall
1.0	LP-1.0Q-M&O, Rev 0	1, 2 & 3	N/A	N/A	N/A	SAT	SAT	CAT
	QAIP 01-02, Rev 15	2	N/A	N/A	N/A	SAT	SAT	SAT
2.0	AP-2.1Q, Rev 2	4-8	N/A	N/A	N/A	SAT	SAT	
	AP-2.2Q, Rev 1	9-10	N/A	N/A	N/A	SAT	SAT	SAT
	AP-2.14Q, Rev 2	11-14	N/A	N/A	N/A	SAT	SAT	SAI
	AP-2.20Q, Rev 0, ICN 1	15-18	N/A	N/A	N/A	SAT	SAT	
3.0	AP-3.10Q, Rev 2, ICN 4	19-22	N/A	N/A	N/A	SAT	SAT	
	AP-3.12Q, Rev 0, ICN 4	23-25	N/A	N/A	N/A	SAT	SAT	SAT
	AP-3.15Q, Rev 3	26-28	N/A	N/A	N/A	SAT	SAT	
5.0	QAIP 5-1, Rev 11	29	N/A	N/A	SAT	SAT	SAT	SAT
	QAIP 20-1, Rev 7	29	N/A	N/A	SAT	SAT	SAT	SAI
6.0	AP-6.28Q, Rev 0, BSCN 1	30-33	N/A	N/A	N/A	SAT	NI	SAT
7.0	AP-7.7Q, Rev 0, ICN 1	34-35	N/A	N/A	N/A	SAT	SAT	SAT
12.0	AP-12.1Q, Rev 0, ICN 1	36-42	N/A	N/A	N/A	SAT	SAT	SAT
15.0	AP-15.2Q, Rev 0, ICN 1	43	N/A	N/A	N/A	SAT	NI	SAT
16.0	AP-16.1Q, Rev 4, ICN 1	44-47	N/A	N/A	N/A	SAT	SAT	SAT
17.0	AP-17.1Q, Rev 2, ICN 1	48-52	N/A	N/A	N/A	SAT	SAT	SAT
Supp. I	AP-SI.1Q, Rev 3, ICN 3	53-60	N/A	N/A	N/A	SAT	SAT	SAT
Supp. II	AP-SII.2Q, Rev 0	61-63	N/A	N/A	N/A	SAT	SAT	SAT
Supp. III	AP-SIII.1Q, Rev 1, ICN 1	64-67	N/A	N/A	SAT	SAT	SAT	
	AP-SIII.2Q, Rev 0, ICN 3	68-69	N/A	N/A	N/A	SAT	SAT	SAT
	AP-SIII.3Q, Rev 1, ECN 1	70-77	N/A	N/A	N/A	SAT	SAT	
Supp. V	AP-SV.1Q, Rev 0, ICN 2	78 - 79	N/A	N/A	N/A	SAT	SAT	SAT

Legend: CDA = Corrected During Audit

DR = Deficiency Report NI = No Implementation SAT = Satisfactory NA = Not Applicable REC = Recommendation

ATTACHMENT 3

ACRONYMS/ABBREVIATIONS

BSC Bechtel SAIC Company, LLC

DOE U.S Department of Energy

DR Deficiency Report

NCR Nonconformance Report NQS Navarro Quality Services

OCRWM Office of Civilian Radioactive Waste Management

OQA Office of Quality Assurance

QA Quality Assurance

QARD Quality Assurance Requirements and Description

RPC Records Processing Center

SBR Software Baseline Request

SN Scientific Notebook

SNL Sandia National Laboratories

TWP Technical Work Plan